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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,356	07/24/2003	Michael R. Hale	VPI/00-122 DIV2 US	1551

27916 7590 11/03/2005

VERTEX PHARMACEUTICALS INC.
130 WAVERLY STREET
CAMBRIDGE, MA 02139-4242

EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,356	HALE ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,18-23 and 27-41* is/are pending in the application.

4a) Of the above claim(s) *23 and 27-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 18-22* is/are rejected.

7)☐ Claim(s) *1,5, 9-13 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13, 18-23 and 27-41 are currently pending in the instant application. Claims 1-9 and 18-22 are rejected, claims 1, 5, 9-13 and 18 are objected and claims 23 and 27-41 are withdrawn from consideration as being for non-elected subject matter.

Inventorship

In view of the papers filed 7/24/2003, the inventorship in this nonprovisional application has been changed by the deletion of Robert Mashal.

Thus, the inventors of the present application are as follows:

Michael R. Hale

James W. Janetka

Francois Maltais

Jingrong Cao

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-13 and 18-22 and the further election of the compound IIA-141 in the reply filed on 1 August 2005 is acknowledged.

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination is:**

The products of the formula I or a pharmaceutically acceptable salt thereof, wherein:

Ht, A-B, R1, T, Q, R, R2, R3, R4, R6, y, R7, R8 and R' are as found in claim 1.

The remaining subject matter of claim 18 not drawn to the above elected invention and the subject matter of claims 23 and 27-41 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of claim 18 wherein T-R2 is not as found in claim 1(T-R2 of claim 1 is wherein T is a valence bond, R2 is aryl substituted with up to three R8 groups, R8 is halogen, 'R' or 'OR' wherein each R' is independently selected from hydrogen or aliphatic), specifically wherein T-R2 is for example, the compounds IIA-92 wherein one R9 is SO2NH2 which is not within the elected invention. Furthermore, the compounds of claim 18 wherein Q-R4 is other than as found in claim 1 is also not within the elected invention, for example, the compounds of IIA-94 and IIA-95 wherein Q is not C(=O) or SO2. The compound of IIA-188 of claim 18 is not within the elected invention as there is no heterocycle, aryl or heteroaryl ring in R4, etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn

compounds differ from those of the elected invention, such as, for example, by not containing a heterocycle, heteroaryl or aryl ring in R4, such as by not containing a C(=O) or SO2 at position Q or by being substituted by other than the R8 substituents of claim 1. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claim 1 objected to because of the following informalities: the term and punctuation "; and" as the last word before the period is considered a typographical error. It is suggested that applicant delete "; and" from before the period in claim 1. Furthermore, it appears that the period of claim 1 has been deleted by the strike-through, it is suggested that applicant end claim 1 with a period. Appropriate correction is required.

Claims 5, 9 and 13 are objected to for being substantial duplicates of the claims from which they depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject

the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k). Specifically, claims 5, 9 and 13 have the same limitation to the values of Q, R1 and R7 as found in the claims from which they depend (claims 4, 8 and 12, respectively).

Claims 10-13 are objected to as being dependent upon a rejected base claim, but would appear allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 18 is objected to as containing non-elected subject matter. Claim 18 presented drawn solely to the elected invention for search and examination as identified supra on page 3 would overcome the instant objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions comprising the compound of the formula I as found in claim 1 and additional therapeutic agents selected from a chemotherapeutic agent, an anti-inflammatory agent, an immunomodulatory or immuosupressive agent, a neurotrophic factor, an agent for treating liver disease, an agent for treating a blood disorder, an agent for treating diabetes, or an agent for treating an immunodeficiency disorder does not reasonably provide enablement for a pharmaceutical composition comprising the compound of the formula I as found in claim 1 and an additional

anti-viral agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a pharmaceutical composition comprising the compound of the formula I as found in claim 1 and additional therapeutic agents selected from a chemotherapeutic agent, an anti-inflammatory agent, an immunomodulatory or immuosupressive agent, a neurotrophic factor, an agent for treating liver disease, an agent for treating a blood disorder, an agent for treating diabetes, an anti-viral agent or an agent for treating an immunodeficiency disorder.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to pharmaceutical compositions comprising multiple active agents, one would need to consider drug-drug interactions.

For the preparation of pharmaceutical compositions containing multiple active ingredients, one needs to take into account drug-drug interactions. There are various types of anti-viral agents known in the prior art, which act by differing mechanisms such as virucidal agents, which directly inactivate viruses, antiviral agents, which inhibit viral replication, and immunomodulators, which boost the host immune response. Some of these anti-viral agents may be incompatible with applicants compound of the formula I due to drug-drug interactions. Taking antiviral drugs with certain other medicines may affect the way the drugs work or

may increase the chance of side effects. As found in Drugs of Today 39(5), 2003, 301-38, Obach discloses that in regards to any given pharmacokinetic drug-drug interaction, the two drugs involved can be considered as either the "perpetrator" drug or the "victim" drug. The perpetrator is the drug that affects the activity of an enzyme of protein involved in the metabolism or disposition of the victim drug. The victim drug is the one that either causes side-effects or toxicity due to increased exposure, or lack of efficacy due to exposure decreased to below that required for therapeutic effect (page 302). There are varying mechanisms of drug interactions such as the reduction in the rate of the metabolim of one drug by another, the irreversible inactivation of drug-metabolizing enzymes and the exposure to the victim drug is decreased (pages 303-304). Obach also discloses that there are a number of in vitro and in vivo experimental approaches to be taken to determine drug-drug interactions (page 304).

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present for the pharmaceutical compositions containing additional therapeutic agents in the instant specification is found on pages 53 and 54. Pages 53 and 54 provide a listing of additional therapeutic agents such as a chemotherapeutic agent, an anti-inflammatory agent, an immunomodulatory or immuosupressive agent, a neurotrophic factor, an agent for treating liver disease, an agent for treating a blood disorder, an agent for treating diabetes, an anti-viral agent or an agent for treating an

immunodeficiency disorder and gives examples of each type of therapeutic agent except anti-viral agent. For example, chemotherapeutic agents useful as additional therapeutic agents the specification page 53 are topotecan and taxol. The specification does not disclose one single example of an anti-viral agent, nor does the specification disclose what the breadth of the term anti-viral agent encompasses. Furthermore, there is no pharmaceutical composition actually prepared in the instant specification which contains any type of anti-viral agent.

The breadth of the claims

The breadth of the claims is pharmaceutical compositions comprising the compound of the formula I as found in claim 1 and additional therapeutic agents selected from a chemotherapeutic agent, an anti-inflammatory agent, an immunomodulatory or immuosupressive agent, a neurotrophic factor, an agent for treating liver disease, an agent for treating a blood disorder, an agent for treating diabetes, an anti-viral agent or an agent for treating an immunodeficiency disorder.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what anti-viral agents could be administered with applicants' instant formula I without any direction found in the specification as to what type of anti-viral agents are considered, and the drug-drug interactions of these agents with the compound of the formula I. While he level of skill in the art is high, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment

of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compositions exhibit the desired pharmacological activity. Thus, the specification fails to provide sufficient support of pharmaceutical compositions of the formula I and an additional anti-viral agent. As a result necessitating one of skill to perform an exhaustive search for which anti-viral agents can be combined with the compound of the formula I without negative drug-drug interactions.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which anti-viral agents could be combined in a pharmaceutical composition with the compound of the formula I, with no assurance of success.

This rejection can be overcome deleting the phrase "an anti-viral agent" from the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. Claim 18 recites the limitation of, for example, compound No. IIA-92, IIA-94 and IIA-95 in the compound according to claim 1. There is insufficient antecedent basis for these limitations in the claim as the compounds of claim 1 contain T-R2 as an aryl group substituted with up to three R8 substituents of which the three R8 substituens are halogen, -R' or OR' wherein each R' is independently selected form hydrogen or aliphatic, and contain Q-R4 as a-C(O) or SO2 group substituted by R6 or NHR6. Claim 18 contains compounds wherein an R8 is SO2NH2, which is not within the compound of claim 1 and contains compounds wherein, for example, Q is not C(=O) or SO2. The compound of IIA-188 of claim 18 is not within the compound of the claim 1 as there is no heterocycle, aryl or heteroaryl ring in R4, etc. This rejection can be overcome by deleting the compounds of claim 18 that are not within the invention of claim 1.

Commonly Assigned

Claims 1-9 and 18-22 are directed to an invention not patentably distinct from claims 1-9 and 11-15 of commonly assigned US application No. 10/919,774. Specifically, the claims 1-9 and 11-15 of commonly assigned US Application No. 10/919,774 are claiming compounds and pharmaceutical compositions which differ from applicants instantly claimed invention only by the position of the functional groups on the isoxazole, i.e. they are positional isomers. For example, claim 12 of the commonly assigned application claims the compound of I-4 which differs only by the position of the functional groups on the isoxazole from applicants instantly claimed compound IIA-23 of claim 18, i.e. they are positional

isomers. Nothing unobvious is seen in substituting one isomer for a structurally similar isomer, as taught by commonly assigned US Application No. 10/919,774 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). Furthermore, a compound that is isomeric with the comparative compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the comparative compound.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Application No. 10/919,774 discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C.

102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Double Patenting

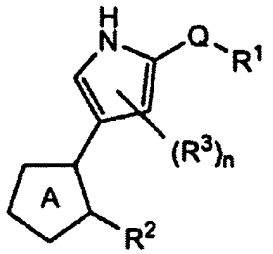
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

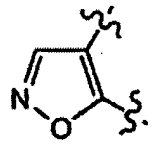
Claims 1-9 and 18-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 11-15 of copending Application No. 10/919,774. Although the conflicting claims are not identical, they are not patentably distinct from each

other because claims 1-9 and 11-14 of copending Application NO. 10/919,774 are claiming compounds, which are positional isomers of the instantly claimed compounds of claims 1-9 and 18-22. Specifically, conflicting claims 1-9 and 18-22 are claiming compounds and pharmaceutical compositions of the formula I:

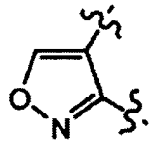


I

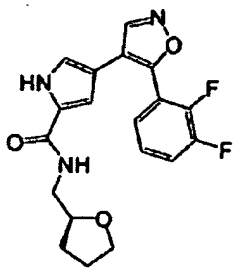
(claim 1) wherein Q can be –C(O)N(R) or C(O) (claims 5 and 6); wherein R1 can be a 3-7 membered saturated or partially unsaturated ring (claims 2-4); wherein n is 0 or 1 (claims 7 or 8), wherein R2 is an optionally substituted phenyl ring (claim 9), wherein Ring A can be



or



(claim 11), for example the compounds of the formula I-2, I-3, I-4, I-6, I-7 or I-8 (claim 12). Claims 13 and 14 are pharmaceutical compositions of the compound of the claim 1. The compound of the formula I-4 is the following formula:



, which is a positional isomer of the compound instantly claimed in applicants claim 18 of the formula IIA-23 as the functional groups on the isoxazole are in different positions. Therefore, the difference between applicants instant claimed invention and the invention of the conflicting claims is that the conflicting claims are drawn to positional isomers of the instant invention and claim specific compounds which are positional isomers of instantly specifically claimed compounds. Nothing unobvious is seen in substituting one isomer for a structurally similar isomer, as taught by commonly assigned US Application No. 10/919,774 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). Furthermore, a compound that is isomeric with the comparative compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the comparative compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under 35 USC 103(a) in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

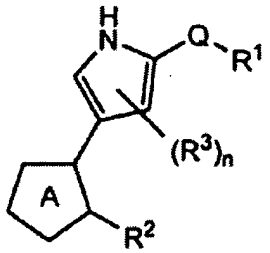
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

As no showing that the inventions were commonly owned at the time the invention in this application was made, claims 1-9 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over conflicting claims 1-9 and 11-15 of commonly assigned US Application No. 10/919,774 as it is not clear that the inventor of the instant application invented the subject matter sought to be patented.

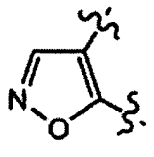
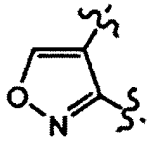
Determining the scope and contents of the Copending Application

Conflicting claims 1-9 and 11-14 of copending Application NO. 10/919,774 are claiming compounds which are positional isomers of the instantly claimed compounds of claims 1-9 and 18-22. Specifically, conflicting claims 1-9 and 18-22 are claiming compounds and pharmaceutical compositions of the formula I:

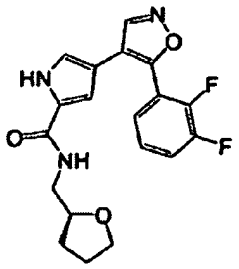


I

(claim 1) wherein Q can be –C(O)N(R) or C(O) (claims 5 and 6); wherein R1 can be a 3-7 membered saturated or partially unsaturated ring (claims 2-4); wherein n is 0 or 1 (claims 7 or 8), wherein R2 is an optionally substituted phenyl ring (claim 9), wherein Ring A can be

 or  (claim 11), for example the compounds of the formula I-2, I-3, I-4, I-6, I-7 or I-8 (claim 12). Claims 13 and 14 are pharmaceutical

compositions of the compound of the claim 1. The compound of the formula I-4 is the following formula:



, which is a positional isomer of the compound instantly claimed in applicants claim 18 of the formula IIA-23 as the functional groups on the isoxazole are in different positions.

Ascertaining the differences between the prior art and the claims at issue

The difference between applicants instant claimed invention and the invention of the conflicting claims is that the conflicting claims are drawn to positional isomers of the instant invention and claim specific compounds which are positional isomers of instantly specifically claimed compounds.

Resolving the level of ordinary skill in the pertinent art

However, nothing unobvious is seen in substituting one isomer for a structurally similar isomer, as taught by commonly assigned US Application No. 10/919,774 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). Furthermore, a compound that is isomeric with the comparative compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the comparative compound.

This rejection could be overcome, for example, by a showing that the inventions were commonly owned at the time the invention in this application was made.

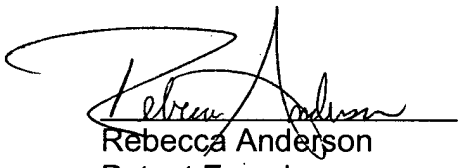
Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



October 27, 2005

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